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3106 '99 APR -5 AIO:56

March 29, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: Neotame


Identifying Information (lb & we)

I am enclosing a scientific paper accepted for publication by the *Western Journal of Medicine*. As such there has to be a confidentiality until publication.

I believe publication is scheduled for April 1999, although this timing is out of my control.

The issues of possible cancer induction need to be fully addressed since the "neotame" metabolism appears to be similar to that of aspartame. Please include this data in your analysis.

Sincerely,



George R. Schwartz, MD

GRS/ri

98F-0052

LET2

# The Western Journal of Medicine

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3105 '99 APR -5 AIO :56

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Dear Dr. Schwartz:

Given the quick acceptance of your report and its passing toward **publication**, we would much appreciate a copy of the report on diskette. We prefer that it be a PC-formatted diskette with the manuscript in Word 6.0/95 or 97 format. Please also do not forget to add the reference number (99-83) to the label of the diskette.

Thanks very much,

Western Journal of Medicine Editorial Office

February 18,1999

Research Report

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## Nutrasweet and Cancer

(1%-titularly Breast, Prostate and Brain Cancers)

There is an extraordinary **epidemiological** connection between Nutrasweet (Aspartame) and cancer. The likelihood of this being a chance finding is small. The observed biochemical mechanism which can explain the correlation offers additional weight to the epidemiologic research finding.

Nutrasweet (aspartame) is composed of linkages of **aspartic acid**, **phenylalanine** and methanol. The **aspartic acid** acts as a neuroexcitatory **agent**.<sup>1</sup> When Nutrasweet is digested, it yields 10% methanol (wood **alcohol**).<sup>2</sup> The wood alcohol (methanol) is widely distributed throughout the body including brain, muscle, fat and **nervous tissue**.<sup>3</sup> It is then metabolized to formaldehyde which enters the cells and binds to the proteins and DNA (the genetic **material**).<sup>4</sup>

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<sup>1</sup>Blaylock, Russell L.: **Excitotoxins: The Taste that Kills**, 1997, Health Press,

<sup>2</sup>Team Nutrasweet, Monsanto Response, 1999,

<sup>3</sup>Osborn H. Alcohol Substitutes. Treatment of Poisonings by Methanol, **Ethylene Glycol** and Isopropyl Alcohol p. **741-5** in Schwartz **GR**, et al. Eds, Principles and Practice of Emergency Medicine, Lippincott/Williams & Wilkins, 1999 .

<sup>4</sup>Trocho, et al. Formaldehyde Derived From Dietary "Aspartame Binds to Tissue Components In Vivo. *Life Sciences* 63(5):337-349, 1998.

Cytogenetic effects (changes in DNA) have been shown to result from formaldehyde exposure<sup>5</sup> and DNA damage occurs from formaldehyde.<sup>6</sup> The nature of the injury generally involves breaking and then creation of cross **linking within the genetic** material which alters the cells. This finding has been confirmed numerous times and the **DNA-protein-cross-links** are believed to cause cancers in experimental animals.<sup>7</sup> Changes in the genetic material is associated with cancer production in **humans**.<sup>8</sup> The ability of Aspartame to cause cellular mutations has been shown through studies by Shephard, et al.<sup>9</sup> There are increases in malignant brain tumors suggested to be associated with aspartame use.<sup>10</sup>

Formaldehyde is a known stimulant for cancer and genetic damage in the **cell**.<sup>1112</sup> Our epidemiologic research demonstrates the following:

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<sup>5</sup>Shaham D, et al. DNA-Protein **Crosslinks: A Biomarker** of Exposure to Formaldehyde. *Carcinogenesis*, Jan. 1996.

<sup>6</sup>Ross WE, McMillan DR, Ross CF: Comparison of DNA Damage by **Methylmelamines** and Formaldehyde, *Journal National Cancer Institute* 67:217-21, 1981.

<sup>7</sup>Cassanova, et al.: DNA-Protein Cross-links and Cell Replication at Specific Sites in the Nose of F344 Rats Exposed **Subchronically** to Formaldehyde, *Fundamental and Applied Toxicology* 223, 535-536, 1994.

<sup>8</sup>Olopade OI, Rowley JD: Recurring Chromosome Re-arrangements in Human Cancer. P. 99-120, in Holland JF et al Eds., Cancer Medicine. 3rd edition, Lea & Febiger, 1993.

<sup>9</sup>Shephard, et al., Mutagenic Activity of Peptides and the Artificial Sweetener Aspartame after Nitrosation. *Fd Chem Toxic* 1993;31:323-29.

<sup>10</sup>Olney JW, et al.: Increasing brain tumor rates: is there a link to aspartame?. *J Neuropath Exp Neurol* 1996 Nov, 55:11, 1115-23.

<sup>11</sup>Cassanova, et al.

<sup>12</sup>Crosby RM, et al: Molecular analysis of formaldehyde-induced mutations in human lymphoblasts and E. Coli. *Environ Mol Mutagen*. 12, 155-166, 1988.

- Rising incidence of breast cancer (more than 180,000 new cases yearly and in women now the single leading cause of death in woman age 35-54<sup>13</sup> ) over 25 years tracking increased aspartame use. (In 1974 Nutrasweet was approved for limited use, in 1983 it was approved for use in diet sodas.)
- Rising incidence of prostate cancer, with 132,000 new cases in 1991 and the second most common cancer in **men**;<sup>14</sup> again, tracking the rise in aspartame use.
- Rising incidence of brain **cancers**<sup>15</sup>

Cancer statistics also note that rates of breast and prostate cancer are 5 to 6 times higher in North American and Europe than in Asia and **Africa**—places where Nutrasweet market penetration has been so far **less**.<sup>16 17</sup> The chart of breast cancer increases demonstrates these pivotal times.

Testing involving Nutrasweet occurred in the 1972-1973 period. Limited approval as a sweetener was granted (in the USA) in 1974 and full unlimited approval was granted in 1983. Arrows on the chart demonstrate the extraordinary concordance with increasing breast cancer rates. A similar finding can be shown with prostate cancer. The likelihood of these being rare coincidence is offset by the biochemical evidence supporting a likely mechanism for cancer induction. In addition, animal experiments, particularly involving mice, did demonstrate **mammary** tumors and urogenital changes in males which were found in initial testing prior to Nutrasweet approval.

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<sup>13</sup>Fisher B, et al.: **Neoplasms** of the Breast. P. 1706-1774, Cancer Medicine, 3rd Ed, Lea & Febiger, 1993.

<sup>14</sup>Trump DL Roberts on Neoplasms of the Prostate, p. 1562-1580, Cancer Medicine, 3rd Ed. Lea & Febiger, '1993.

<sup>15</sup>Olney, see 10.

<sup>16</sup> Fisher, see 13.

<sup>17</sup> Trump, see 14.

The **epidemiological** correlations are striking and raise the hypothesis of some biochemical or physical link. While there are many potential pathways, we are postulating the most direct. **Nutrasweet** converts to methanol, which goes to intracellular formaldehyde. The latter affects DNA causing cell toxicity and chromosome abnormalities which precipitate cancers in susceptible people. Nutrasweet has already been shown to induce mammary tumors and testicular changes in experimental animals. <sup>18</sup> Based on the epidemiologic associations, and biochemical effects at the cellular-DNA level, Nutrasweet and aspartame should be **carefully** studied as a potential environmental cause of well over one million cases of cancer.

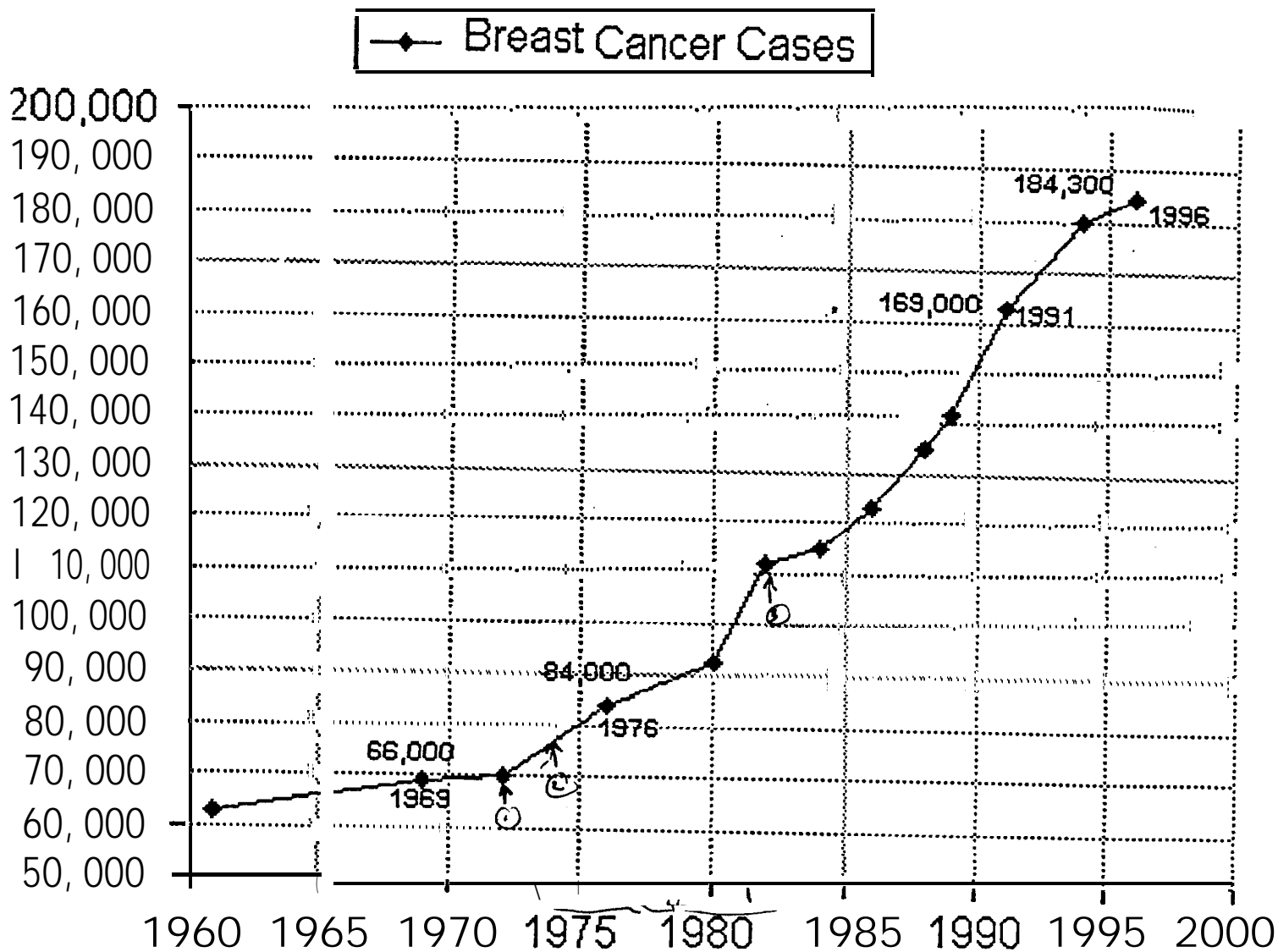
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<sup>18</sup>GP Searle research reported to FDA 1971-74, released under Freedom of Information Act.

Ref # 99-83

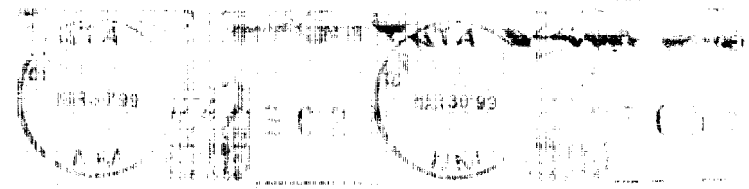
FROM SEER DATA

# Breast Cancer Cases



- ① testing
- ② limited approval
- ③ unlimited
- ④ 1974 - 1981  
extensive testing

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